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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,810	11/17/2003	Shengwen Li	ALLE0004-100 (17614(BOT))	5198

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/715,810	LI ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-72 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-72 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U. S. C. 121:

I. Claims 1, 2, 5-11 and 18-21, drawn to a method of treating a botulinum toxin intoxication in a mammal comprising administering a rescue agent, wherein the rescue agent comprises an inactive botulinum toxin, classified in class 424, subclass 9.1, and class 435, subclass 236.1.

II. Claims 1, 3, 12-16 and 18-21, drawn to a method of treating a botulinum toxin intoxication in a mammal comprising administering a rescue agent, wherein the rescue agent comprises a compound of a modified non-toxic nonhemagglutinin, modified HA70 or HA34, classified in class 424, subclass 9.1, and class 530, subclass 350.

III. Claims 1, 4 and 17-21, drawn to a method of treating a botulinum toxin intoxication in a mammal comprising administering a rescue agent, wherein the rescue agent comprises an inactive botulinum toxin and a modified nontoxic nonhemagglutinin, classified in class 424, subclass 9.1, and class 435, subclass 236.1.

IV. Claims 22-35, 37-51, 70 and 71, drawn to a botulinum toxin which is glycosylated, or having reduced antigenicity, or having reduced antigenicity and is inactive, classified in class 530, subclass 350, and class 435, subclass 236.1.

V. Claims 36 and 72, drawn to a method of treating a muscular condition, an autonomic nervous system disorder or pain comprising administering a botulinum toxin which is glycosylated or inactive, or having reduced antigenicity, classified in class 424, subclass 9.1, and class 435, subclass 236.1.

VI. Claims 52-56, drawn to a modified non-toxic nonhemagglutinin comprising a nontoxic nonhemagglutinin and a target moiety, classified in class 530, subclass 350.

VII. Claims 57-64 and 66-69, drawn to a method of making a di-chain botulinum toxin in a non-Clostridium botulinum cell, and a non-Clostridium botulinum cell comprising a vector operatively harboring a nucleotide sequence encoding a single chain botulinum toxin and a vector operatively harboring a nucleotide sequence encoding a nontoxic nonhemagglutinin, classified in class 435, subclasses 235.1 and 325.

VIII. Claim 65, drawn to a method of making a di-chain botulinum toxin in cell free system, classified in class 435, subclasses 6 and 236.1.

Should Group II or VI be elected, applicant is required to select a molecule as a targeting moiety in the modified nontoxic nonhemagglutinin from claim 15 or 55. Each molecule which has different structure and function is patentably distinct. This is not species election.

2. The inventions are distinct, each from the other because of the following reasons:

The product of Invention IV and the methods of Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of Inventions I and V are alternative processes of use of the product of Invention IV.

The product of Invention VI and the method of Invention II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another

materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the method of Invention II can be practiced with a pentavalent vaccine that protects against botulinum toxins (paragraph [0023] of the specification).

The product of Invention IV is distinct from the product of Invention VI because they have different structures and are physically and functionally distinct chemical entities, e.g., the product of Invention IV is a glycosylated or modified botulinum toxin, while the product of Invention VI is a modified nontoxic nonhemagglutinin comprising a nontoxic nonhemagglutinin and a targeting moiety.

The product of Invention IV is related to the cell of Invention VII because the product can be produced by expression in the cell. The inventions are distinct because they are physically and functionally distinct chemical entities and the toxin can be made by another process such as protein synthesis in a cell free system.

The product of Invention VI is distinct from the product of Invention VII because they physically and functionally distinct chemical entities, e.g., the product of Invention VII is a modified nontoxic nonhemagglutinin, while the product of Invention VII is a cell comprising a vector.

The method of Invention VII and the product of Invention of IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process

(MPEP § 806.05(f)). In the instant case the product of Invention of IV can be made by synthesis in a cell free system (the method of Invention VIII).

The method of Invention VIII and the product of Invention of IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of Invention of IV can be made by expression in a host cell (the method of Invention VII).

The methods of Inventions I, II, III, V, VII and VIII are distinct from each other because the method steps, the materials used and the outcomes are wholly different among I, II, III, V, VII and VIII.

The product of Invention IV is distinct from the methods of Inventions II and III because the product of Invention IV can be neither made by nor used in the methods of Inventions II and III.

The product of Invention VI is distinct from the methods of Inventions I, III, V, VII and VIII because the product of Invention VI can be neither made by nor used in the methods of Inventions I, III, V, VII and VIII.

The product of Invention VII is distinct from the methods of Inventions I, II, III, V and VIII because the product of Invention VII can be neither made by nor used in the methods of Inventions I, II, III, V and VIII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications and recognized divergent

subject matter, and because inventions I-VIII require different searches but are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

CMK
November 13, 2004